REMARKS

Applicant thanks the Examiner for his clear and helpful comments in the Office Action dated May 9, 2005.

Lonidamine has been shown in Phase II clinical studies sponsored by the assignee of the instant application to have a rapid and significant therapeutic effect when administered to men with BPH. Results from these clinical studies are reported in Ditonno *et al.*, 2005, "Clinical evidence supporting the role of lonidamine for the treatment of BPH" *Rev. Urol.* 7(suppl 7):S27-33, a copy of which is enclosed. The Ditonno *et al.* reference reports that after a 28-day course of treatment with lonidamine, subjects with BPH experienced an average decrease in prostate volume of greater than 10%, an average decrease in International Prostate Symptom Scores (IPSS) of more than 7 points, a significant increase in urine flow, and other beneficial results.

To expedite issuance of claims to this important new therapy for BPH, the claims are amended herewith to focus on subject matter Applicant believes has been indicated by the Office to be allowable (*e.g.*, a method of treatment of BPH comprising administering lonidamine). All claim amendments and cancellations are made without prejudice to future prosecution of the originally claimed subject matter.

Rejections Under Section 112, First Paragraph

Claims 1-15 were rejected because the Office stated that the specification, while enabling for *treating* BPH, does not enable *prophylaxis* of BPH. Although Applicant disagrees, the claims have been amended to no longer recite "prophylaxis," thus overcoming this rejection.

Applicant thanks the Examiner for suggesting that this rejection could also be overcome by replacing "prophylaxis" with a reference to reducing symptoms of BPH as described in the specification at paragraph [0017]. New claims 24-27 have been added, and are directed to a method for reducing a symptom associated with BPH in a human subject not under treatment for cancer or diagnosed with cancer. These claims are believed to be allowable.

Rejections Under Section 112, Second Paragraph

Claims 1, 7, 16, and 17 were rejected as indefinite in the recitation of the term "analog." These claims have been amended to no longer recite this term, thus overcoming this rejection.

Claims 5, 6, 11, 12, and 20 were rejected as indefinite in the recitation of the term "about." Claims 5, 6, 11, and 12 have been amended and no longer recite this term, thus overcoming this rejection. Claim 20 has been cancelled.

Claim Objections and Rejections Under Section 102(b) and 103(a)

Claim 18 was objected to and was rejected as allegedly anticipated by Besner *et al.*. Claims 18-20 were rejected as allegedly obvious in view of the combination of Kim *et al.*, Hu *et al.* and Molnar-Kimber *et al.*. These rejections and objections are mooted by the cancellation of claims 18-20.

Additional Comments

Amendments to the specification correct minor typographical or editorial errors and add the application number for a copending U.S. patent application originally identified by attorney docket number and filing date. Paragraph [0031] is amended to correct an error and thereby avoid redundancy in the specification. In the instant specification, the terms "BPH," "benign prostatic hyperplasia" and "benign prostatic hypertrophy" are used interchangeably. Support for the amendment is found in Claim 1 as originally filed. In the amendment of paragraph [0076], because "low dosing" is underlined in the original specification, the added language, "prophylaxis", is identified by double underline as specified in 68 *Fed. Reg.* 38615 (June 30, 2003).

Claim 1 has been amended to recite that a therapeutically effective amount of lonidamine is administered. This amendment is made to improve clarity and not to change the scope of the claim. Support is found in at least paragraph [0020] of the specification. The amendment to claim 2 finds support in at least paragraphs [0076] and [0086] of the specification. In addition, to make the terminology of claim 1 consistent with the title, the claim has been amended to recite "hyperplasia" in place of "hypertrophy." No change in scope or meaning is intended.

New claims 21-23 and 26-27 are directed to administration dosages and find support in at least original claims 9 and 10 and paragraph [0089] of the specification.

The amendments to the specification and claims are believed not to add new matter.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

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Respectfully submitted,

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Enclosure: Ditonno *et al.*, 2005, "Clinical evidence supporting the role of lonidamine for the treatment of BPH" *Rev. Urol.* 7(suppl 7):S27-33